

REMARKS

The Office Action of December 12, 2006 has been carefully reviewed and these remarks are responsive thereto. Reconsideration and allowance of the instant application are respectfully requested in view of the amendments and remarks presented in this response.

Claims 1-2, 4-13, and 15-28 are pending in this application. By this Amendment, claims 1, 2, 4, 11, 12, 25, 26, and 28 have been amended, previously-withdrawn claims 16-24 have been cancelled, and new claims 29-38 have been added. Claims 1-2, 4-8, 11-13, 15 and 25-28 stand rejected.

Examiner's Request for Additional Information

Applicants have located an electronic copy of slides that were projected in connection with the presentation made by K. Ranji Vaidyanathan at the event described by "Symposium Y," and Applicants have included a printed copy of said slides in an Information Disclosure Statement filed herewith. This presentation corresponds to the Abstract cited as Walish *et al.* in the Office Action. Applicants have no knowledge of any copies of these slides or other related handouts being distributed in connection with the Symposium, either in written or electronic format. Accordingly, neither the slides nor the presentation constitutes a "printed publication" under 35 U.S.C. § 102(b). See *Regents of the University of California v. Howmedica, Inc.*, 530 F.Supp. 846, 860, 210 U.S.P.Q. 727, 738-39 (D. N.J. 1981) (projection of slides at a lecture did not constitute a "printed publication" when the projection "was limited in duration and could not disclose the invention to the extent necessary to enable a person of ordinary skill in the art to make or use the invention," and "the public did not have access to the slides prior to the critical date, and ... no prints of the slides were made prior to said date"). See also *In re Klopfenstein*, 380 F.3d 1345, 72 U.S.P.Q.2d 1117 (Fed. Cir. 2004) (public accessibility is the "criterion by which a prior art reference will be judged for the purposes of § 102(b)"; relevant factors include "the length of time the display was exhibited, the expertise of the target audience, the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied, and the simplicity or ease with which the material displayed could have been copied").

Unlike the slides in *Klopfenstein*, which were printed and pasted onto posterboards and displayed continuously for two and a half days, the slides from Dr. Vaidyanathan's presentation were only used for projection during the presentation. Applicants have no reason to believe the

slides were ever reduced to print and disseminated and/or displayed publicly for a time sufficient to allow the material to be copied prior to the critical date. Thus, these slides, and the accompanying presentation, cannot be considered printed publications under § 102(b), and cannot be used to reject Applicants' claims.

Claim Rejections Under 35 USC §112

Claims 1-2, 4-8, 11-13, 15, and 26-27 are rejected under 35 USC §112, first paragraph, as failing to comply with the enablement requirement. In summary, the Office Action asserts that the terms "resorbable composition" and "predetermined period of time" are not disclosed in the specification.

Applicants submit that the compositions described as being resorbable, for example, PEEK and PBT, are indeed resorbable, as shown by Applicants' testing results reported in Tables 4-8 in Applicants' specification. These testing results suggested that the materials degrade by hydrolytic surface erosion *in vivo*. (See Page 24, Ln. 30-31). It is true that PEEK and PBT degrade at a relatively slow rate, which can be advantageous. Nevertheless, Applicants have demonstrated degradation and resorbability of PEEK and PBT in their testing. However, in an effort to expedite prosecution and gain allowance of the claims, Applicants have amended the claims to remove the term "resorbable," as there is no need to so limit the claims at this time. Thus, the rejections on this ground have been addressed.

Additionally, Applicants submit that the meaning of the phrase, "a predetermined period of time" appears to be misinterpreted. Applicants are not claiming a composition that provides load-bearing support only for a predetermined period of time. Rather, Applicants are claiming a composition that provides load-bearing support for at least a predetermined period of time. The specification discloses, in one example, that the substrate composition provides load bearing support for one year or more. (Page 9, Ln. 10-11; See also Tables 4-8). Thus, Applicants have demonstrated that a period of time can be determined, over at least which period the substrate composition will provide load-bearing support. However, again, in an effort to expedite prosecution and gain allowance of the claims, Applicants have amended the claims to remove the term "predetermined," as there is no need to so limit the claims at this time. Thus, the rejections on this ground have been addressed.

Claims 4-8 and 27 are rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claim 4 has been amended to depend directly from claim 1, and Applicants submit that the rejection has been addressed.

Claim Rejections Under 35 USC §103

In the Office Action, claims 1, 2, and 4-8 were not rejected under 35 U.S.C. § 103. Accordingly, since the Examiner's rejections under § 112 have been addressed, Applicants submit that claims 1, 2, and 4-8 are allowable.

A. Priority of Claims 1, 29, and 34

Applicants submit that, regardless of the Examiner's interpretation of the provisional applications, at least independent claim 1 is entitled to a filing date of January 2, 2001. Claim 1 does not recite any of the elements the Examiner asserts are not disclosed in the provisional applications (i.e. polyglycolic acid, polylactic acid-polyglycolic acid copolymer, or their combination with polycaprolactone). New independent claims 29 and 34 also do not recite any of these elements. Thus, at least claims 1, 29, and 34 are clearly supported by the disclosure of 60/259,348, and are entitled to the filing date of that provisional application.

B. Rejections of Claims 11-13, 15, 25-26, and 28

Claims 11-13 and 15 are rejected under 35 USC §103(a) for being unpatentable over Walish, Vaidyanathan, Sarangapani, Chandra, Harajanto, and Calvert, Symposium Y ("Walish") in view of U.S. Patent No. 6,228,117 to DeBruijn et al. ("De Bruijn"), in further view of U.S. Patent No. 6,534,084 to Vyakarnam et al. ("Vyakarnam"). Claims 25-26 and 28 are rejected under 35 USC §103(a) for being unpatentable over Walish in view of DeBruijn, in further view of U.S. Publication No. 2002/0127391 to Kumar ("Kumar"). Applicants respectfully traverse the rejections.

Even if Walish and/or Kumar are considered to be prior art to independent claims 11 and 25, the combination of the cited references does not disclose, teach or suggest the claimed invention. Independent claim 11 relates to a biomedical implant that includes a porous structure formed from a thermoplastic material selected from the group consisting of

polybutyleneterephthalate, polyethyletherketone, and combinations thereof, where the porous structure has a porosity between about 25% to about 70% by volume and a pore size between about 100 to about 2400 μm . The implant also includes a composition for enhancing the rate of bone growth including a polymer material selected from the group consisting of polylactic acid, polyglycolic acid, polylactic acid-polyglycolic acid copolymer, polycaprolactone, and combinations thereof. Independent claim 25 relates to methods of repairing or replacing tissue that include forming a biocompatible substrate including a polymer composite selected from the group consisting of polybutyleneterephthalate, polyethyletherketone, and combinations thereof, and a growth-enhancing composition including a polymer material selected from the group consisting of polylactic acid, polyglycolic acid, polylactic acid-polyglycolic acid copolymer, polycaprolactone, and combinations thereof. The biocompatible substrate has a porosity between about 25% to about 70% by volume and a pore size between about 100 to about 2400 μm .

Importantly, none of the cited prior art references disclose at least the use of a polymer composite or substrate that includes PBT or PEEK alone, or combinations thereof. Applicants argued this lack of disclosure in the previous submission, and the Office Action contains no response to Applicants' arguments and does not point out the disclosure of this element in the cited references. For at least this reason, the cited references cannot render independent claims 11 and 25 obvious.

Walish discloses porous implants made from slowly-degradable polyesters that are impregnated with a biodegradable polyester/hydroxyapatite blend. However, Walish does not disclose the use of PBT or PEEK, or that the porous implants have any specific pore size or porosity. Walish also does not disclose that the implants also include compositions for enhancing the rate of bone growth including polylactic acid, polyglycolic acid, polylactic acid-polyglycolic acid copolymer, polycaprolactone, a calcium source, or combinations thereof.

DeBruijn discloses a device for facilitating cell growth *in vitro*, prior to implantation of the device. DeBruijn discloses that the device is made of a thermoplastic polymer and provides examples of a PEO/PBT copolymer. However, DeBruijn, like Walish, fails to disclose a device made of PEEK or PBT alone, or a combination thereof.

Additionally, one skilled in the art would not use the teachings of DeBruijn in combination with those of Walish, because DeBruijn teaches the formation of bone-like cellular

matrix *in vitro*, rather than after implantation (see, e.g., Col. 4, lines 17-21; Col. 9, lines 28-32). Accordingly, one skilled in the art would not refer to DeBruijn in designing an implant for enhancing the formation of bone *in vivo*. Moreover, in Example 1, DeBruijn teaches that the effectiveness of the copolymer to calcify and form a mineralized extracellular matrix decreased as the amount of PBT in the copolymer increased (see, e.g., Col. 5, line 50 – Col. 6, line 3). Thus, DeBruijn also teaches away from a device made of PBT alone, or containing large amounts of PBT.

Vyakarnam discloses an interconnected, open cell porous foam, made of a material such as caprolactone. Thus, Vyakarnam fails to disclose a substrate made of PBT or PEEK, or a combination thereof.

Kumar discloses a coating for a substrate, such as a plate, where the coating includes a ceramic in a resorbable polymer binder. The ceramic preferably is a phosphate, carbonate, bicarbonate or sulfate, and the polymer is composed of lactic acid, glycolic acid, amides, anhydrides, orthoesters, and dioxanones. Thus, Kumar fails to disclose a substrate made of PBT or PEEK, or a combination thereof.

Accordingly, Walish, DeBruijn, Vyakarnam, and Kumar, either alone or in combination, do not disclose, teach or suggest the invention claimed in independent claims 11 and 25, as well as any of the dependent claims, and the claims pending in the present application are not obvious. In view of the above, reconsideration and allowance of the pending claims are respectfully requested.

New Claims

New independent claims 29 and 34 are entitled to a filing date of January 2, 2001, as stated above. Accordingly, certain cited references, particularly Walish, are not citable as prior art to claims 29 and 34. Thus, because Walish cannot be relied upon as a prior art reference, claims 29 and 34 are patentable, and Applicants respectfully request examination and allowance thereof.

CONCLUSION

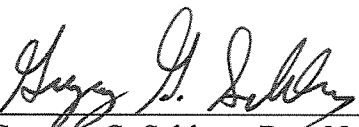
In view of the above amendments and remarks, prompt reconsideration and full allowance of claims 1-2, 4-8, 11-13, 15 and 25-28 in the subject application are respectfully requested. All rejections have been addressed. Applicants also request examination and allowance of new claims 29-38. Applicants respectfully submit that the instant application is in condition for allowance and respectfully solicit prompt notification of the same.

The Commissioner is authorized to debit or credit our Deposit Account No. 19-0733 for any fees due in connection with the filing of this response.

The Examiner is invited to contact the undersigned at the number set forth below should the Examiner believe that a further conversation would be useful in the prosecution of this case.

Respectfully submitted,

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